45 CFR 425.700-710

§ 425.700 General rules.

(a) CMS shares aggregate reports with the ACO.

(b) CMS shares beneficiary identifiable data with ACOs on the condition that the ACO, its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and comply with the terms of the data use agreement described in this subpart.

(c) The ACO must not limit or restrict appropriate sharing of medical record data with providers and suppliers both within and outside the ACO in accordance with applicable law.

§ 425.704 Beneficiary-identifiable data.

Subject to providing the beneficiary with the opportunity to decline data sharing as described in this §425.708, and subject to having a valid DUA in place, CMS, upon the ACO's request for the data for purposes of evaluating the performance of its ACO participants or its ACO providers/suppliers, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health, will provide the ACO with beneficiary identifiable claims data for preliminary prospective assigned beneficiaries and other beneficiaries who receive primary care services from an ACO participant upon whom assignment is based during the agreement period.

(a) If an ACO wishes to receive beneficiary identifiable claims data, it must sign a DUA and it must submit a formal request for data. ACOs may request data as often as once per month.

(b) The ACO must certify that it is requesting claims data about either of the following:

(1) Its own patients, as a HIPAA-covered entity, and the request reflects the minimum data necessary for the ACO to conduct its own health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(2) The patients of its HIPAA-covered entity ACO participants or its ACO providers/suppliers as the business associate of these HIPAA covered entities, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of those participants.

(c) The use of identifiers and claims data will be limited to developing processes and engaging in appropriate activities related to coordinating care and improving the quality and efficiency of care that are applied uniformly to all Medicare beneficiaries with primary care services at the ACO, and that these data will not be used to reduce, limit or restrict care for specific beneficiaries.

(d) To ensure that beneficiaries have a meaningful opportunity to decline having their claims data shared with the ACO, the ACO may only request claims data about a beneficiary if—

(1) The beneficiary name appears on the preliminary prospective assignment list found on the initial or quarterly aggregate report, or has received primary care services from an ACO participant upon whom assignment is based (under Subpart E of this part), during the agreement period.

(2) The beneficiary has been notified in writing how the ACO intends to use beneficiary identifiable claims data in order to improve the quality of care that is furnished to the beneficiary and, where applicable, coordinate care offered to the beneficiary; and

(3) The beneficiary did not exercise the opportunity to decline having his/her claims data shared with the ACO as provided in §425.708.

(e) At the ACO's request, CMS continues to provide ACOs with updates to the requested beneficiary identifiable claims data, subject to beneficiary's opportunity to decline data sharing under §425.708.

(f) If an ACO requests beneficiary identifiable information, compliance with the terms of the data use agreement described in §425.710 is a condition of an ACO's participation in the Shared Savings Program.

§ 425.706 Minimum necessary data.

(a) ACOs must limit their identifiable data requests to the minimum necessary to accomplish a permitted use of the data. The minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

(1) Beneficiary ID.

(2) Procedure code.

(3) Gender.

(4) Diagnosis code.

(5) Claim ID.

(6) The from and through dates of service.

(7) The provider or supplier ID.

(8) The claim payment type.

(9) Date of birth and death, if applicable.

(10) TIN.

(11) NPI.

(b) The minimum necessary Part D data elements may include but are not limited to the following data elements:

(1) Beneficiary ID.

(2) Prescriber ID.

(3) Drug service date.

(4) Drug product service ID.

(5) Quantity dispensed.

(6) Days supplied.

(7) Brand name.

(8) Generic name.

(9) Drug strength.

(10) TIN.

(11) NPI.

(12) Indication if on formulary.

(13) Gross drug cost.

§ 425.710 Data use agreement.

(a)(1) Before receiving any beneficiary identifiable data, ACOs must enter into a DUA with CMS. Under the DUA, the ACO must comply with the limitations on use and disclosure that are imposed by HIPAA, the applicable DUA, and the statutory and regulatory requirements of the Shared Savings Program.

(2) If the ACO misuses or discloses data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the DUA, it will no longer be eligible to receive data under subpart H of this part, may be terminated from the Shared Savings Program under §425.218, and may be subject to additional sanctions and penalties available under the law.

(b) [Reserved]

Subpart I—Reconsideration Review Process